

# OTC Cough/Cold Drug Products

## 21 C.F.R. Part 341

The following table summarizes the individual cough/cold ingredients, including dosage levels, that are generally recognized as safe and effective for use in OTC cough/cold preparations when formulated and labeled in compliance with the final regulations at 21 C.F.R. Part 341.

Cough/cold preparations that contain these ingredients at the levels specified in the regulations are misbranded (section 503(b)(4)(B)) if they are marketed as prescription drug products, unless the preparation also contains an ingredient that is limited to prescription dispensing requirements.

The single ingredients may be combined in OTC cough/cold drug products only as provided in 21 C.F.R. § 341.40.

The regulations in 21 C.F.R. § 341.90 provide directions for use that may be included in professional labeling for certain age groups for several pharmacological categories. The directions for use for the age groups cited in this section may not be placed on the product container or any labeling that is available to the consumer. This information may **only** be in material that is supplied separately to a health professional.

For all pharmacological categories, the regulations do not include directions for use for children under 2 years of age. The directions for use on the labeling for all products should read “Under 2 years of age, ask a doctor” unless the monograph specifies that the product should not be used by older age groups except as directed by a doctor.

This table is provided only as a guide to assist interested manufacturers and marketers of OTC cough/cold drug products in determining if their products are in compliance with existing regulations. It is critical that the regulations in 21 C.F.R. Part 341 be followed if a firm wishes to market an OTC cough/cold drug that does not require an approved application. Manufacturers should be aware that they need to convert the labeling in 21 C.F.R. Part 341 to the “Drug Facts” format required by 21 C.F.R. Section 201.66.

Table of OTC Cough/Cold Ingredients and Dosage Ranges: 21 CFR 341

<b>Ingredients by Pharmacological Category</b>	<b>Dosage: Adult and children 12 years and older</b>	<b>Dosage: Children 6 to Under 12 years</b>	<b>Dosage: Children 2 to Under 6 years</b>
	<b>Every 4 hrs unless otherwise stated</b>	<b>Every 4 hrs unless otherwise stated</b>	<b>Every 4 hrs unless otherwise stated</b>
<b>Antihistamines:</b>			
Brompheniramine maleate	4 mg. (4 to 6 hrs)	2 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Chlorcyclizine HCl	25 mg. (6 to 8 hrs)	Ask a doctor <sup>1</sup>	Ask a doctor <sup>1</sup>
Chlorpheniramine maleate	4 mg. (4 to 6 hrs)	2 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Dexbrompheniramine maleate	2 mg. (4 to 6 hrs)	1 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Dexchlorpheniramine maleate	2 mg. (4 to 6 hrs)	1 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Diphenhydramine HCl	25 to 50 mg. (4 to 6 hrs)	12.5 to 25 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Diphenhydramine citrate	38 to 76 mg. (4 to 6 hrs)	19 to 38 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Doxylamine succinate	7.5 to 12.5 mg. (4 to 6 hrs)	3.75 to 6.25 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Phenindamine tartrate	25 mg. (4 to 6 hrs)	12.5 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Pheniramine maleate	12.5 to 25 mg. (4 to 6 hrs)	6.25 to 12.5 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Pyrilamine maleate	25 to 50 mg. (6 to 8 hrs)	12.5 to 25 mg. (6 to 8 hrs)	Ask a doctor <sup>1</sup>
Thonzylamine HCl	50 to 100 mg. (4 to 6 hrs)	25 to 50 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Triprolidine HCl	2.5 mg. (4 to 6 hrs)	1.25 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
<b>Antitussives</b>			
<b>Oral:</b>			
Chlophedianol HCL	25 mg. (6 to 8 hrs)	12.5 mg. (6 to 8 hrs)	Ask a doctor <sup>1</sup>
Codeine	10 to 20 mg. (4 to 6 hrs)	5 to 10 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>

<b>Ingredients by Pharmacological Category</b>	<b>Dosage: Adult and children 12 years and older</b>	<b>Dosage: Children 6 to Under 12 years</b>	<b>Dosage: Children 2 to Under 6 years</b>
	<b>Every 4 hrs unless otherwise stated</b>	<b>Every 4 hrs unless otherwise stated</b>	<b>Every 4 hrs unless otherwise stated</b>
Codeine phosphate	10 to 20 mg. (4 to 6 hrs)	5 to 10 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Codeine sulfate	10 to 20 mg. (4 to 6 hrs)	5 to 10 mg. (4 to 6 hrs)	Ask a doctor <sup>1</sup>
Dextromethorphan	10 to 20 mg. (4 hrs) 30 mg. (6 to 8 hrs)	5 to 10 mg. (4 hrs) 15 mg. (6 to 8 hrs)	2.5 to 5 mg. (4 hrs) 7.5 mg. (6 to 8 hrs)
Dextromethorphan HBr	10 to 20 mg. (4 hrs) 30 mg. (6 to 8 hrs)	5 to 10 mg. (4 hrs) 15 mg. (6 to 8 hrs)	2.5 to 5 mg. (4 hrs) 7.5 mg. (6 to 8 hrs)
Diphenhydramine citrate	38 mg. (4 hrs)	19 mg. (4 hrs)	Ask a doctor <sup>1</sup>
Diphenhydramine HCl	25 mg. (4 hrs)	12.5 mg. (4 hrs)	Ask a doctor <sup>1</sup>
<b>Topical:</b>			
Camphor (ointment)	4.7 to 5.3% (up to 3 times daily)	4.7 to 5.3% (up to 3 times daily)	4.7 to 5.3% (up to 3 times daily)
Menthol (ointment)	2.6 to 2.8% (up to 3 times daily)	2.6 to 2.8% (up to 3 times daily)	2.6 to 2.8% (up to 3 times daily)
Menthol (lozenge)	5 to 10 mg. (every hour as needed)	5 to 10 mg. (every hour as needed)	5 to 10 mg. (every hour as needed)
Camphor (steam)	6.2% (up to 3 times daily)	6.2% (up to 3 times daily)	6.2% (up to 3 times daily)
Menthol (steam)	3.2% (up to 3 times daily)	3.2% (up to 3 times daily)	3.2% (up to 3 times daily)
<b>Bronchodilators:</b>			
Ephedrine	12.5 to 25 mg. (4 hrs)	Ask a doctor <sup>1</sup>	Ask a doctor <sup>1</sup>
Ephedrine HCl	12.5 to 25 mg. (4 hrs)	Ask a doctor <sup>1</sup>	Ask a doctor <sup>1</sup>
Ephedrine sulfate	12.5 to 25 mg. <b>(4 hrs)</b>	Ask a doctor <sup>1</sup>	Ask a doctor <sup>1</sup>
Epinephrine	1% (spray) (1-3 inhalations every 3 hrs)	1% (spray) (1-3 inhalations every 3 hrs)	4 to under 6 years: <sup>2</sup> 1% (spray) (1-3 inhalations every 3 hrs)

<b>Ingredients by Pharmacological Category</b>	<b>Dosage: Adult and children 12 years and older</b>	<b>Dosage: Children 6 to Under 12 years</b>	<b>Dosage: Children 2 to Under 6 years</b>
	<b>Every 4 hrs unless otherwise stated</b>	<b>Every 4 hrs unless otherwise stated</b>	<b>Every 4 hrs unless otherwise stated</b>
Epinephrine bitartrate	1% (spray) (1-3 inhalations every 3 hrs)	1% (spray) (1-3 inhalations every 3 hrs)	4 to under 6 years: <sup>2</sup> 1% (spray) (1-3 inhalations every 3 hrs)
Racephedrine HCl	12.5 to 25 mg. <b>(4 hrs)</b>	Ask a doctor <sup>1</sup>	Ask a doctor <sup>1</sup>
Racepinephrine HCl	1% (spray) (1-3 inhalations every 3 hrs)	1% (spray) (1-3 inhalations every 3 hrs)	4 to under 6 years: <sup>2</sup> 1% (spray) (1-3 inhalations every 3 hrs)
<b>Expectorant:</b>			
Guaifenesin	200 to 400 mg. (4 hrs)	100 to 200 mg. (4 hrs)	50 to 100 mg. (4 hrs)
<b>Nasal Decongestants:</b>			
<b>Oral:</b>			
Phenylephrine HCl	10 mg. (4 hrs)	5 mg. (4 hrs)	2.5 mg. (4 hrs)
Pseudoephedrine HCl	60 mg. (4 to 6 hrs – max. 4 doses)	30 mg. (4 to 6 hrs – max. 4 doses)	15 mg. (4 to 6 hrs – max. 4 doses)
Pseudoephedrine sulfate	60 mg. (4 to 6 hrs – max. 4 doses)	30 mg. (4 to 6 hrs – max. 4 doses)	15 mg. (4 to 6 hrs – max. 4 doses)
<b>Topical:</b>			
Levmetamfetamine	0.04 to 0.15 mg. per 800 mL air (inhalant) - 2 inhalations every 2 hours	0.04 to 0.15 mg. per 800 ml. air (inhaler) 1 inhalation every 2 hours	Ask a doctor
Ephedrine, Ephedrine HCl, or Ephedrine sulfate	0.5% nasal spray or drops – 2 or 3 not more often than every 4 hours	0.5% nasal spray or drops – 1 or 2 not more often than every 4 hours	Ask a doctor

Ingredients by Pharmacological Category	Dosage: Adult and children 12 years and older	Dosage: Children 6 to Under 12 years	Dosage: Children 2 to Under 6 years
Ephedrine, Ephedrine HCl, or Ephedrine sulfate	Every 4 hrs unless otherwise stated 0.5% nasal jelly Small amt. <b>not more often than every 4 hrs</b>	Every 4 hrs unless otherwise stated 0.5% nasal jelly Small amt. <b>not more often than every 4 hrs</b>	Every 4 hrs unless otherwise stated Ask a doctor
Naphazoline HCl <b>(need to add entry for drops &amp; sprays)</b>	0.05% jelly – small amt. not more often than every 6 hours	0.025% jelly – small amt. not more often than every 6 hours	Ask a doctor
Oxymetazoline HCl	0.05% spray/drops - 2 or 3 not more often than every 10 – 12 hours	0.05% spray/drops - 2 or 3 not more often than every 10 – 12 hours	0.025% spray/drops – <b>calibrated dose - 2 or 3 not more often than every 10 – 12 hours</b>
Oxymetazoline HCl	0.05% jelly – small amt. not more often than every 10 - 12 hours	0.05% jelly – small amt. not more often than every 10 - 12 hours	Ask a doctor
Phenylephrine HCl	0.25% or 0.5% or 1% - spray/drops – 2 or 3 <b>not more often than every 4 hours</b>	0.25% - spray/drops - 2 or 3 <b>not more often than every 4 hours</b>	0.125% spray/drops – <b>calibrated dose – 2 or 3 not more often than every 4 hours</b>
Phenylephrine HCl	0.25% or 0.5% or 1% - nasal jelly – small amt. <b>not more often than every 4 hours</b>	0.25% - nasal jelly – small amt. <b>not more often than every 4 hours</b>	Ask a doctor
Propylhexedrine	0.4 mg. to 0.5 mg. /800 mL air (inhalant) – <b>2 inhalations</b> not more often than every 2 hours.	0.4 mg. to 0.5 mg. /800 mL air (inhalant) – <b>2 inhalations</b> not more often than every 2 hours.	Ask a doctor
Xylometazoline HCl <b>(need to add entry for nasal jelly)</b>	0.1% spray/drops – 2 or 3 not more often than every 8 to 10 hours	0.05% spray/drops – <b>calibrated dose - 2 or 3 not more often than every 8 to 10 hours</b>	0.05% spray/drops – <b>calibrated dose - 2 or 3 not more often than every 8 to 10 hours</b>

Footnotes:

1. Professional labeling for selected age group(s) provided in 21 C.F.R. § 341.90
2. For epinephrine spray and racepinephrine spray: Under 4 years of age, ask a doctor